

REMARKS

The Examiner has required a restriction to one of the following inventions under 35 U.S.C. § 121:

- I. Claims 5-17, 19, 25, 28-30, 37-41, and 67-74 in part and 1, 26, drawn to a polypeptide comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification relative to a wild-type Fc region, such that said polypeptide binds an FcγR with an altered affinity relative to a polypeptide comprising a wild-type Fc region, classified in class 530, subclass 387.1+, for example.
- II. Claims 5-17, 19, 25, 28-30, 37-41, and 67-74 in part, and 2, 3, 4, 27 drawn to drawn to a polypeptide comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification relative to a wild-type Fc region, such that said polypeptide binds an FcγRIIIA with a greater affinity than a comparable polypeptide comprising the wild-type Fc region binds FcγRIIIA, classified in class 530, subclass 387.1+, for example.
- III. Claims 38 and 71-74 in part, and 4, 18, 25, 27 drawn to a polypeptide comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification relative to a wild-type Fc region, such that said polypeptide specifically binds FcγRIIIA with a greater affinity than a comparable polypeptide comprising the wild-type Fc region binds FcγRIIIA, and said polypeptide further specifically binds FcγRIIB with a lower affinity than a comparable polypeptide comprising the wild-type Fc region binds FcγRIIB, provided that said variant Fc region does not have an alanine at any of positions 256, 298, 333, or 334, classified in class 530, subclass 387.1+, for example.
- IV. Claims 20-24 and 42-46 in part, drawn to a nucleic acid comprising a nucleotide sequence encoding a polypeptide comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification relative to a wild-type Fc region, such that said polypeptide binds an FcγR, classified in class 536, subclass 23.1, for example.

- V. Claims 20-24 and 42-46 in part, drawn to a nucleic acid comprising a nucleotide sequence encoding a polypeptide comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification relative to a wild-type Fc region, such that said polypeptide binds an FcγRIIIA, classified in class 536, subclass 23.1, for example.
- VI. Claims 31-36 in part, drawn to a method of treating cancer in a patient having a cancer characterized by a cancer antigen, said method comprising administering to said patient a therapeutically effective amount of an antibody comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification relative to a wild-type Fc region, such that said polypeptide binds an FcγRIIIA with a greater affinity than a comparable polypeptide comprising the wild-type Fc region binds FcγRIIIA, classified in class 514, subclass 2, for example.
- VII. Claims 31-36 in part, drawn to a method of treating cancer in a patient having a cancer characterized by a cancer antigen, said method comprising administering to said patient a therapeutically effective amount of an antibody comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification relative to a wild-type Fc region, such that said polypeptide specifically binds FcγRIIIA with a greater affinity than a comparable polypeptide comprising the wild-type Fc region binds FcγRIIIA, and said polypeptide further specifically binds FcγRHB with a lower affinity than a comparable polypeptide comprising the wild-type Fc region binds FcγRHB, provided that said variant Fc region does not have an alanine at any of positions 256, 298, 333, or 334, classified in class 514, subclass 2, for example.
- VIII. Claims 47 and 51-55, drawn to a method for producing a tetrameric FcγR complex, wherein said tetrameric complex has an enhanced affinity for an Fc region, relative to the affinity of a monomeric FcγR for the Fc region, classified in class 435, subclass 71.1+.
- IX. Claims 48-50, drawn to tetrameric FcγR complex, classified in class 530, subclass 387.1+, for example.
- X. Claims 56 and 57 in part, drawn to a method of treating or managing cancer in a patient having a cancer characterized by a cancer antigen, said method comprising

administering to said patient a therapeutically effective amount of an antibody comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification relative to a wild-type Fc region, such that said polypeptide binds an FcγR with an altered affinity relative to a polypeptide comprising a wild-type Fc region, classified in class 514, subclass 2, for example.

- XI. Claims 56 and 57 in part, drawn to a method of treating or managing cancer in a patient having a cancer characterized by a cancer antigen, said method comprising administering to said patient a therapeutically effective amount of an antibody comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification relative to a wild-type Fc region, such that said polypeptide binds an FcγRIIIA with a greater affinity than a comparable polypeptide comprising the wild-type Fc region binds FcγRIIIA, classified in class 514, subclass 2, for example.
- XII. Claims 56 and 57 in part, drawn to a method of treating or managing cancer in a patient having a cancer characterized by a cancer antigen, said method comprising administering to said patient a therapeutically effective amount of an antibody comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification relative to a wild-type Fc region, such that said polypeptide specifically binds FcγRIIIA with a greater affinity than a comparable polypeptide comprising the wild-type Fc region binds FcγRIIIA, and said polypeptide further specifically binds FcγRIIB with a lower affinity than a comparable polypeptide comprising the wild-type Fc region binds FcγRIIB, provided that said variant Fc region does not have an alanine at any of positions 256, 298, 333, or 334, classified in class 514, subclass 2, for example.
- XIII. Claims 58-65, drawn to a method of treating an autoimmune disorder in a patient in need thereof, said method comprising administering to said patient a therapeutically effective amount of a molecule comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification relative to a wild type Fc region, such that said molecule specifically binds FcγRIIB with a greater affinity than a comparable molecule comprising the wild type Fc region, and said molecule further specifically binds FcγRIIIA with a lower affinity than a

comparable molecule comprising the wild type Fc region, class 514, subclass 2, for example.

- XIV. Claim 66, drawn to a method of treating an infectious disease in a patient in need thereof, said method comprising administering to said patient a therapeutically effective amount of a molecule comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification relative to a wild type Fc region, such that said molecule specifically binds FcγRIIB with a greater affinity than a comparable molecule comprising the wild type Fc region, and said molecule further specifically binds FcγRIIA with a lower affinity than a comparable molecule comprising the wild type Fc region, classified in class 514, subclass 2, for example.
- XV. Claims 75 and 76, drawn to a polypeptide comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification relative to a wild-type Fc region, such that said polypeptide specifically binds Fc.γ.3.1 with a greater affinity than a comparable polypeptide comprising the wild-type Fc region, and said polypeptide further specifically binds Fc.γ.2.2 with a lower affinity than a comparable polypeptide comprising the wild type Fc region binds Fc.γ.2.2, wherein said at least one amino acid modification comprises a set of substitutions selected from the group consisting of a substitution as listed in claim 75, classified in class 530, subclass 387.1+, for example.
- XVI. Claim 78, drawn to a polypeptide comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification, wherein said at least one amino acid modification comprises substitution at position 255 with glutamic acid and at position 396 with leucine, classified in class 530, subclass 387.1+, for example.
- XVII. Claim 79, drawn to a polypeptide comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification, wherein said at least one amino acid modification comprises substitution at position 370 with glutamic acid and at position 396 with leucine, classified in class 530, subclass 387.1+, for example.

- XVIII. Claim 80, drawn to a polypeptide comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification, wherein said at least one amino acid modification comprises substitution at position 392 with threonine and at position 396 with leucine, classified in class 530, subclass 387.1+, for example.
- XIX. Claim 81, drawn to a polypeptide comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification, wherein said at least one amino acid modification comprises substitution at position 221 with glutamic acid, at position 270 with glutamic acid, at position 308 with alanine, at position 311 with histidine, at position 396 with leucine, and at position 402 with aspartic acid, classified in class 530, subclass 387.1+, for example.
- XX. Claim 82, drawn to a polypeptide comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification, wherein said at least one amino acid modification comprises substitution at position 243 with leucine, at position 305 with isoleucine, at position 378 with aspartic acid, at position 404 with serine, and at position 396 with leucine, classified in class 530, subclass 387.1+, for example.
- XXI. Claim 83, drawn to a polypeptide comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification,
Application/Control Number: 10/754,922 Art Unit: 1643 wherein said at least one amino acid modification comprises substitution at position 284 with methionine, at position 298 with asparagine, at position 334 with glutamic acid, at position 355 with tryptophan, and at position 416 with threonine, classified in class 530, subclass 387.1+, for example.

The Examiner has also required that a single autoimmune disorder be elected as a species if the invention of Group XIII is elected.

The Examiner contends that Groups I-XXI are patentably distinct. In particular, the Examiner alleges that products claimed in each of Groups I, II, III, IV, IX, XV, XVI, XVII, XVIII, XIX, XX and XXI are separate and distinct, made by materially different methods, and used in materially different methods that have different modes of operation, functions and effects. The Examiner further alleges that searching the inventions of all groups would

require different searches in the relevant literature and consideration of differing patentability issues.

In response, Applicants hereby elect Group I, directed to claims 5-17, 19, 25, 28-30, 37-41, and 67-74 in part, and claims 1 and 26, drawn to a polypeptide comprising a variant Fc region, wherein said variant Fc region comprises at least one amino acid modification relative to a wild-type Fc region, such that said polypeptide binds and FcγR with an altered affinity relative to a polypeptide comprising a wild-type Fc region, classified in class 530, subclass 387.1+. Applicants' provisional election, with traverse, of Group I renders the species election in connection with Group XIII moot.


Upon the allowance of the product claims, Applicants request that any withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claims be rejoined in accordance with the provisions of M.P.E.P. § 821.04.

Applicants fully reserve the right to prosecute the subject matter of the non-elected inventions in one or more related applications.

Applicants respectfully request that the above remarks and amendments be entered and made of record in the file history of the instant application.

Respectfully submitted,

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